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| EXAMINER | |
|---|---|
| TOTH, KAREN E | |

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| 3735 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/661,658 | PINEDA ET AL. | |
| | Examiner | Art Unit | |
| | Karen E. Toth | 3735 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-9 and 11-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claim Rejections - 35 USC § 103*

2. Claims 1, 4, 5, 7, 8, 15, and 16 are rejected under 35 U.S.C. 103(a) as being anticipated by Knispel (US Patent 4883067) in view of Kim (US Patent Application Publication 2003/0109797).

Regarding claim 1, Knispel discloses a method comprising acquiring a plurality of bioelectric signals from an individual (column 9, lines 14-24); determining a multi-dimensional cognitive-emotive profile of the individual based on the signals (column 3, lines 64-68; column 18, lines 36-43); and mapping the profile onto a set of commands for controllably delivering brain stimulation commands to the individual for therapeutic and non-therapeutic (column 8, lines 20-22) stimulus intervention (column 3, lines 43-68; column 12, lines 54-56; column 14, lines 14-28; figure 9), in order to effect a prolonged change in the individual's cognitive-emotive profile (column 18, lines 36-38). Knispel does not disclose determining the profile by using the bioelectric signals to determine a current psychological state, and comparing that state to a set of templates or indices to extract the profile.

Kim teaches a method of altering a patient's cognitive-emotive profile comprising obtaining a plurality of bioelectric signals from the patient and using them to determine the patient's current psychological state (paragraphs [0011], [0015], [0036], [0039]),

comparing the patient's present state to a reference model, or set of indices (paragraphs [0012]-[0013]), and using that comparison to determine a cognitive-emotive profile (paragraphs [0038]-[0039], where the chromatic bar color is indicative of the profile), in order to provide a calibrated and accurate representation of the patient's state. It would have been obvious to one of ordinary skill in the art to have made the system of Knispel and used a comparison between a current state and a reference state to determine the cognitive-emotive profile, as taught by Kim, in order to provide a calibrated and accurate representation of the profile.

Regarding claim 4, Knispel further discloses that the bioelectric signal may be an EEG signal (column 9, lines 14-24).

Regarding claim 5, Knispel further discloses that the EEG may be recorded from multiple sites on the individual's scalp (column 17, lines 27-32) using a portable headset (shown on user 1 with elements 3 and 11 in figure 1).

Regarding claim 7, Knispel further discloses decomposing the EEG signal into frequency domain subcomponents (column 4 line 61 to column 5 line 22), time domain subcomponents (column 9 line 43 to column 10 line 13), and spatial domain (column 9, lines 19-24; column 17, lines 26-32).

Regarding claim 8, Knispel further discloses the frequency domain subcomponents consisting of alpha and beta waves (column 17, lines 32-46).

Regarding claim 11, Knispel further discloses analyzing the subcomponents using FFT (column 10, lines 30-31).

Regarding claims 15 and 16, Knispel further discloses dynamically determining a cognitive-emotive profile that reflects changing behavior states (column 10, lines 13-18) and is comprised of sensorimotor and psychological states and their boundary conditions (column 19, lines 7-14).

3. Claims 2 and 3, are rejected under 35 U.S.C. 103(a) as being unpatentable over Knispel in view of Kim, as applied to claims 1, 4, 5, 7, 8, 11, 15, and 16 above, and further in view of Epstein (US Patent 6132361).

Knispel discloses all the elements of the current application, as described above, except for the brain stimulation commands being effected by transcranial magnetic stimulation (TMS) that is delivered to at least one site on a body. Epstein teaches a method of using TMS to provide brain stimulation feedback commands to an individual in response to measured emotive signals (column 1, lines 61-63; column 4, lines 15-22) to at least one site on the user's body (figure 3), since use of TMS to provide brain stimulation is well known in the art of cognitive-emotive studies. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Knispel in view of Kim and used TMS to provide brain stimulation, as taught by Epstein, since use of TMS to provide brain stimulation is well known in the art of cognitive-emotive studies.

4. Claims 6 and 9 are is rejected under 35 U.S.C. 103(a) as being unpatentable over Knispel in view of Kim, as applied to claims 1, 4, 5, 7, 8, 11, 15, and 16 above, and further in view of Price (US Patent 6983184).

Regarding claim 6, Knispel in view of Kim discloses all the elements of the current invention, as described above, except for the portable headset including a matrix of EEG sensors and magnetic field coils oriented over specific areas of the individual's brain. Price teaches a method of applying brain stimulation in response to monitoring EEG signals using a portable headset with a matrix of EEG sensors (elements 2) and a magnetic coil (element 24) oriented over specific areas of an individual's brain (figure 1), in order to ensure accurate sensing and stimulation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Knispel in view of Kim and used a portable headset with a matrix of EEG sensors and a magnetic field coil oriented over specific areas of the individual's brain, as taught by Price, in order to ensure accurate sensing and stimulation.

Regarding claim 9, Knispel in view of Kim discloses all the elements of the current invention, as described above, except for the time domain subcomponents being selected from a group of event-related potentials (ERPs). Price teaches a method of applying brain stimulation in response to monitoring EEG signals that includes monitoring ERPs (column 10, lines 52-56), in order to ensure the reliability of the monitoring. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Knispel in view of Kim and monitored ERPs, as taught by Price, in order to ensure the reliability of the monitoring.

5. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knispel in view of Kim, as applied to claims 1, 4, 5, 7, 8, 11, 15, and 16 above, and further in view of DuRousseau (US Patent Application Publication 2002/0077534).

Regarding claims 12 and 13, Knispel in view of Kim discloses all the elements of the current invention, as disclosed above, except for identifying and classifying feature clusters from the plurality of EEG signal subcomponents. DuRousseau teaches a method of analyzing EEG signals comprising identifying and classifying feature clusters using fuzzy logic with a feature map (paragraphs [0011]-[0012], [0030], [0035]-[0036], [0044], [0047]), in order to accurately identify features within the signals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Knispel in view of Kim and identified and classified feature clusters from the EEG signal subcomponents using fuzzy logic to create a feature map, as taught by DuRousseau, in order to accurately identify features within the signals.

Regarding claim 14, DuRousseau further teaches using real-time pattern recognition to provide feedback instructions (paragraph [0049]), in order to modify the subject's brain activity. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Knispel in view of Kim and DuRousseau and used pattern recognition to provide feedback instructions, as taught by DuRousseau, in order to determine optimal brain stimulation (neural activation) to be provided, as taught by Knispel.

6. Claims 17-20, 23, and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knispel in view of Epstein.

Regarding claim 17, Knispel discloses a system comprising means for acquiring an EEG signal from an individual (column 9, lines 14-24); means for determining a cognitive-emotive profile of the individual based on the EEGs (column 3, lines 64-68; column 18, lines 36-43); and means for controllably delivering brain stimulation commands to the individual in response to the cognitive-emotive profile (column 3, lines 43-68; column 10, lines 13-18; column 12, lines 54-56; column 14, lines 14-28; figure 9), and interactive means for effecting persistent changes to the profile (column 18, lines 36-38). Knispel does not disclose the brain stimulating feedback signal being in the form of TMS.

Epstein teaches a method of using TMS to provide brain stimulation feedback to an individual in response to measured emotive signals (column 1, lines 61-63; column 4, lines 15-22), since use of TMS to provide brain stimulation is well known in the art of cognitive-emotive studies.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Knispel, and included TMS means for brain stimulation, as taught by Epstein, since use of TMS to provide brain stimulation is well known in the art of cognitive-emotive studies.

Regarding claims 18 and 19, Knispel further discloses decomposing the EEG signal into frequency domain subcomponents (column 4 line 61 to column 5 line 22),

time domain subcomponents (column 9 line 43 to column 10 line 13), and spatial domain (column 9, lines 19-24; column 17, lines 26-32).

Regarding claim 20, Knispel further discloses the frequency domain subcomponents consisting of alpha and beta waves (column 17, lines 32-46).

Regarding claim 23, Knispel further discloses using Fast Fourier Transform (FFT) analysis to analyze the EEG signal (column 10, lines 30-31).

Regarding claim 27, Knispel further discloses the cognitive-emotive profile comprising sensorimotor and psychological states and their boundary conditions (column 19, lines 7-14).

Regarding claim 28, Knispel further discloses the system comprising feedback signal to control the amount of brain stimulation being delivered (column 3, lines 58-61).

Regarding claim 29, Knispel further discloses that the signal acquisition means comprises a sensor (element 3).

Regarding claims 30 and 31, Knispel further discloses the processor comprising a central processing unit (CPU) and software control program (column 10, lines 18-21).

Regarding claim 32, Epstein further teaches using the TMS to reduce the symptoms of an illness (column 1, lines 17-18; column 1 line 61 to column 2 line 62; column 13 line 1 to column 14 line 40; figures 5, 6), in order to effectively treat the disease. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the system of Knispel in view of Epstein to reduce the symptoms of an illness, as taught by Epstein, since the effectiveness of TMS is well known in the art.

7. Claims 21 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knispel in view of Epstein, as applied to claims 17-20, 23, and 27-31 above, and further in view of Price.

Regarding claim 21, Knispel in view of Epstein discloses all the elements of the current invention, as described above, except for the time domain subcomponents being selected from a group of event-related potentials (ERPs). Price teaches a system for applying brain stimulation in response to monitoring EEG signals that includes monitoring ERPs (column 10, lines 52-56), in order to ensure the reliability of the monitoring. It would have been obvious to one of ordinary skill in the art at the time the invention was made to made the system of Knispel in view of Epstein, and monitored ERPs, as taught by Price, in order to ensure the reliability of the monitoring.

Regarding claim 32, Knispel in view of Epstein discloses all the elements of the current invention, as described above, except for the interactive means integrating a combinatorial TMS stimulation sequence with a combinatorial EEG recording sequence. Price teaches a system for effecting persistent changes in a cognitive emotive state (column 4, lines 33-36) comprising an interactive system including a combinatorial TMS stimulation sequence with a combinatorial EEG recording sequence (figures 1 and 2), in order to deliver effective and accurate stimulation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included with the system of Knispel in view of Epstein a combinatorial TMS stimulation sequence with a combinatorial EEG recording sequence to interactively effect persistent cognitive

emotive changes, as taught by Price, in order to deliver effective and accurate stimulation.

8. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knispel in view of Epstein, as applied to claims 17-20, 23, and 27-30 above, and further in view of DuRousseau.

Regarding claims 24 and 25, Knispel in view of Epstein discloses all the elements of the current invention, as disclosed above, except for identifying and classifying feature clusters from the plurality of EEG signal subcomponents. DuRousseau teaches a system for analyzing EEG signals comprising identifying and classifying feature clusters using fuzzy logic with a feature map (paragraphs [0011]-[0012], [0030], [0035]-[0036], [0044], [0047]), in order to accurately identify features within the signals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Knispel and Epstein, and identified and classified feature clusters from the EEG signal subcomponents using fuzzy logic to create a feature map, as taught by DuRousseau, in order to accurately identify features within the signals.

Regarding claim 26, DuRousseau further teaches using real-time pattern recognition to provide feedback instructions (paragraph [0049]), in order to modify the subject's brain activity. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Knispel in view of Epstein and DuRousseau and used pattern recognition to provide feedback instructions, as taught

by DuRousseau, in order to determine optimal brain stimulation (neural activation) to be provided, as taught by Knispel.

***Response to Arguments***

9. Applicant's arguments with respect to claims 1, 4, 5, 7, 8, 15, and 16 have been considered but are moot in view of the new ground(s) of rejection.

Additionally, Applicant has argued that Knispel teaches away from the present invention because the stimulation signal is provided audibly, while the present invention does not require the patient to have hearing. The Examiner disagrees with this conclusion, because providing audible signals is not in any sort of opposition to the signals provided by TMS – it is merely an alternate method of providing stimulation. As such, one of ordinary skill in the art could readily choose an alternate means for providing brain stimulation, such as TMS. Applicant also argues that there is no teaching of how to convert audio signals into electronic signals. This argument is not convincing, as the combination of Knispel and Epstein would be an invention that provides the brain stimulation as TMS *instead* of music, and there is no need to convert from audio to electronic signals.

Further, Applicant's argument that Epstein does not use TMS to drive stimulus intervention is not persuasive, since Epstein clearly uses TMS to provide stimulation commands; the purpose of those commands is determined by Knispel. Applicant also argues that Epstein does not use TMS to effect prolonged changes to the patient's

cognitive emotive profile, such as elimination of symptoms of an illness; the Examiner disagrees, since Epstein states that TMS may be used to treat depression (see above).

The rejections stand as FINAL.

***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent Application Publication 2003/0013981 to Gevins, which discloses similar inventions.

US Patent Application Publication 2006/0029198 to Dorneich, which discloses similar inventions.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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